Claims:

We claim

1. A pharmaceutical gastro-retentive delivery system for controlled release of therapeutically active agent in stomach or upper part of gastro-intestinal tract in the form of bilayer dosage form which comprises,
   a) a first layer (layer-A) which is responsible for retaining the dosage form in stomach or upper part of gastro-intestinal tract (spatial control) for a prolonged period, comprising of pharmaceutical excipients having low bulk density, selected from a mixture consisting of
      (i) polymers selected from ethylcellulose or suitable enteric polymers of cellulose derivatives and
      (ii) hydrogenated oils, waxes, fatty acids either alone or in combination; optionally with other pharmaceutical aids;
   b) a second layer (Layer- B) which is responsible for prolonged or controlled drug delivery (temporal control) of therapeutic agent which comprises of the active agent and controlled release matrix polymers optionally with other pharmaceutical aids.

2. The delivery system as claimed in claim 1 wherein said pharmaceutical excipient with low bulk density is ethyl cellulose in combination with hydrogenated oils.
3. The delivery system as claimed in any preceding claims wherein the ratio of ethylcellulose and hydrogenated oils is in the range of 95:5 to 30:70.
4. The delivery system as claimed in claim 1 wherein said pharmaceutical aids are selected from pharmaceutical lubricants, antiadherents and glidants.
5. The delivery system as claimed in claim 4, wherein said pharmaceutical aids are selected from magnesium stearate, talc, colloidal silicon dioxide, stearic acid, magnesium stearate fumerate, glyceryl behenate and hydrogenated oils or combination thereof.
6. The delivery system as claimed in claim 1 wherein said controlled release matrix polymers is selected from synthetic or semisynthetic cellulose derivatives like hydroxypropyl methylcellulose, ethylcellulose, hydroxypropylcellulose, methylcellulose, sodium carboxymethylcellulose, natural polymers such as xanthan

gum, gelatin, synthetic polymers, acrylic acid derivatives and polyvinyl acetate or mixtures thereof.

7. The delivery system as claimed in claim 1 wherein said pharmaceutical aids are selected from group of pharmaceutical fillers, disintegrants, lubricants, binders, antiadherents and glidants or combinations thereof.

8. The delivery system as claimed in claim 7 wherein said pharmaceutical disintegrants are selected from crosslinked polyvinylpyrrolidone, crosslinked sodium carboxymethyl cellulose, sodium starch glycolate, microcrystalline cellulose, starch, and pregelatinized starch or their combinations.

9. The delivery system as claimed in claim 7 wherein said pharmaceutical binders are selected from natural polymers selected from starch or gum including acacia, tragacanth, gelatin or synthetic polymers selected from polyvinyl pyrrolidone, methyl cellulose, ethyl cellulose, hydroxypropyl methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose.

10. The delivery system as claimed in claim 7 wherein said pharmaceutical antiadherents, glidants and lubricants are selected from magnesium stearate, talc, colloidal silicon dioxide, stearic acid, salts of stearic acid, magnesium stearate fumarate, glyceryl behenate and hydrogenated oils.

11. The delivery system as claimed in claim 1, wherein said therapeutically active agent is in the form of a raw powder, dispersed or embedded in a suitable liquid, semisolid, micro- or nanoparticles, micro- or nanospheres, a tablet, a caplet, or in a suitable processable form.

12. The delivery system as claimed in claim 1, wherein said therapeutically active agent is a drug having a narrow absorption window in the gastrointestinal tract.

13. The delivery system as claimed in claim 1, wherein said therapeutically active agent is selected from the group consisting of therapeutic, chemotherapeutic, antibiotic antidiabetic, anti-cancers, anti-fungals, anti-filarial, antiviral agents, lipid lowering agents, analgesics, non-steroidal anti-inflammatory agents, anti-ulcer agents, anti-epileptics, anti-gout, immunosuppressants, drugs for respiratory therapy, dopaminergic agents, skeletal muscle relaxants, cardiovascular agents, antipsychotics or those drugs which does not show uniform absorption characteristic throughout the length of the gastrointestinal tract.

14. The delivery system as claimed in claim 1, wherein said therapeutically active agent may also be a drug for local treatment of the gastrointestinal tract.

15. The delivery system as claimed in claim 1, wherein said therapeutically active agent is selected from antibacterial/anti-infective agents, such as ofloxacin, ciprofloxacin, cefuroxime, cefatrizine, cefpodoxime, clarithromycin, loracarbef, azithromycin, cefadroxil, cefixime, amoxycillin; antivirals, such as acyclovir; cardiovascular agents, such as diltiazem, captopril; lipid lowering agents such as simvastatin, lovastatin, atorvastatin; non-steroidal anti-inflammatory agents such as etodolac, ketorolac; anti-ulcer agents such as ranitidine, famotidine; drugs for respiratory diseases, such as fexofenadine, pseudoephedrine, phenylpropanolamine, dextromethorphan, chlorpheniramine; dopaminergic agents, such as bromocriptine; immunosuppressants, such as cyclosporin; skeletal muscle relaxants, such as baclofen; anti-gout agents, such as allopurinol; antidiabetic agents such as acarbose, glipizide.

16. Use of the delivery system as claimed in claim 1, for treatment of disease conditions as described in any preceding claims above.

17. The delivery system as claimed in any preceding claim wherein the layers A & B are prepared by technique selected from melt granulation, wet granulation or direct compression.

18. The delivery system as claimed in any preceding claim wherein the amount of therapeutically active agent is present in an amount ranging from about 0.2 to 1000 mg.

19. The delivery system as claimed in 1 wherein the dosage form floats on the surface of the gastric fluid for prolonged period ranging from 0.5 to 10 hours.

20. The delivery system as claimed in any preceding claims which is optionally coated with rapidly dissolving water soluble film forming polymer or rapidly dissolving pharmaceutical excipient.

21. A drug delivery system as claimed in any preceding claim which includes tablets, caplets or tablets filled in capsules..

22. A pharmaceutical composition prepared according to the present invention suitable for humanadministration.